

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-61. (Cancelled)

62. (Currently amended) A composition comprising: an isolated HIV Tat protein; ~~fragment or mutant~~ in combination with a pharmaceutically acceptable carrier or excipient, wherein said isolated HIV Tat protein; ~~fragment or mutant~~ is biologically active, as shown by the ability of said isolated HIV Tat protein; ~~fragment or mutant~~ to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, and the ability of said isolated HIV Tat protein to do one or both of the following (i) and (ii):

- (i) ~~become internalized by~~ enter and localize in the nuclei of activated endothelial cells or dendritic cells, which ~~internalization~~ entering and localizing is determined by (a) incubating activated endothelial cells or dendritic cells with up to 1 µg/ml of said isolated HIV Tat protein; ~~fragment or mutant~~ which is labeled with rhodamine, and (b) detecting the presence or absence of rhodamine in the activated endothelial cells or dendritic cells by fluorescence microscopy; or
- (ii) activate the proliferation, migration, and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said isolated HIV Tat protein; ~~fragment or mutant~~ is present at a concentration of up to 1 µg/ml; ~~or~~
- ~~(iii) — activate virus replication when said isolated HIV Tat protein; fragment or mutant is added to HIV-1 infected cells at a concentration of up to 1 µg/ml, which activation is determined by (a) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein; fragment or~~

~~mutant, or (b) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid,~~

wherein said composition is pharmaceutically acceptable for administration to a human, ~~wherein the amino acid sequence of said mutant is SEQ ID NO:4, 6 or 8, and wherein the amino acid sequence of said fragment is SEQ ID NO:16 or 17.~~

63. (Currently amended) The composition of claim 62, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is purified.

64. (Cancelled)

65. (Currently amended) The composition of claim 62, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is a wild type HIV Tat protein.

66. (Previously presented) The composition of claim 62, 63 or 65, wherein the administration is selected from the group consisting of mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal, systemic, and local administration.

67. (Cancelled)

68. (Currently amended) The composition of claim 63, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is purified by a method comprising performing heparin affinity chromatography.

69. (Currently amended) The composition of claim 68, wherein said performing step is followed by steps of (a) lyophilizing said isolated HIV Tat protein, ~~fragment or mutant~~, and (b) resuspending said lyophilized isolated HIV Tat protein, ~~fragment or mutant~~ in a degassed buffer.

70-88. (Cancelled)

89. (Previously presented) The composition of claim 62, 63 or 65 which further comprises a biologically acceptable fluid.

90. (Previously presented) A product which is produced by a process comprising lyophilizing the composition of claim 62, 63 or 65.

91. (Previously presented) A product which is produced by a process comprising lyophilizing the composition of claim 62, 63 or 65 and resuspending the lyophilized composition in a biologically acceptable fluid.
92. (Currently amended) The composition of claim 65, wherein the amino acid sequence of said wild type HIV Tat protein consists of ~~SEQ ID No. 2~~ SEQ ID NO:2.
93. (Previously presented) The composition of claim 89, wherein the biologically acceptable fluid is serum, plasma, or one or more fractions thereof.
94. (Previously presented) The product of claim 91, wherein the biologically acceptable fluid is serum, plasma, or one or more fractions thereof.
95. (Previously presented) The composition of claim 62, 63, 65, or 69 which further comprises an adjuvant.
96. (Previously presented) The composition of claim 95 which further comprises a biologically acceptable fluid.
97. (Previously presented) The composition of claim 95, wherein the adjuvant is RIBI, alum, or ISCOM, or a combination thereof.
98. (Currently amended) The composition of claim 62, 63 or 65, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is bound to a delivery vehicle.
99. (Previously presented) The composition of claim 98, wherein said delivery vehicle is a nanoparticle.
100. (Previously presented) The composition of claim 98, wherein said delivery vehicle is an autologous erythrocyte.
101. (Previously presented) The composition of claim 66, wherein the administration is systemic.
102. (Previously presented) The composition of claim 66, wherein the administration is intradermal.

103. (Previously presented) The composition of claim 66, wherein the administration is subcutaneous.

104. (Cancelled)

105. (Previously presented) The composition of claim 66, wherein the administration is mucosal.

106. (Previously presented) The composition of claim 95, wherein the administration is selected from the group consisting of mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal, systemic, and local administration.

107. (Previously presented) The composition of claim 106, wherein the administration is systemic.

108. (Previously presented) The composition of claim 106, wherein the administration is intradermal.

109. (Previously presented) The composition of claim 106, wherein the administration is subcutaneous.

110. (Previously presented) The composition of claim 109 which further comprises Alum.

111. (Previously presented) The composition of claim 106, wherein the administration is mucosal

112. (Currently amended) The composition of claim 62, 63, 65, or 69, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is conjugated to a T-helper peptide or T-helper universal epitope of Tetanus Toxoid.

113. (Cancelled)

114. (Previously presented) The composition of claim 62, 63, 65, or 69, which further comprises HIV rev, nef or gag, or an immunogenic fragment thereof.

115. (Cancelled)

116. (Previously presented) The composition of claim 62, 63, 65, or 69, which further comprises an immuno-modulant cytokine.

117. (Previously presented) The composition of claim 116, wherein said immuno-modulant cytokine is IL-12 or IL-15.

118. (Cancelled)

119. (Currently amended) The composition of claim 62, 63, 65, or 69, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is fused to HIV rev, nef or gag, or an immunogenic fragment thereof.

120. (Cancelled)

121. (Currently amended) The composition of claim 62, 63, 65, or 69, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is fused to an immuno-modulant cytokine.

122. (Previously presented) The composition of claim 121, wherein said immuno-modulant cytokine is IL-12 or IL-15.

123. (Previously presented) The composition of claim 62, 63, 65, or 69, which further comprises an inhibitor of viral replication.

124-141. (Cancelled)

142. (Currently amended) The composition of claim 62 which comprises a combination of said isolated HIV Tat protein, ~~fragment and mutant~~.

143. (Currently amended) The composition of claim 62 or 63 which is suitable for inducing an immune response in the human to said isolated HIV Tat protein, ~~fragment and mutant~~.

144. (Previously presented) The composition of claim 65, wherein said wild type HIV Tat protein is purified.

145. (Previously presented) The composition of claim 92, wherein said wild type HIV Tat protein is purified.

146. (Currently amended) The composition of claim 62, wherein said isolated HIV Tat protein, ~~fragment and mutant~~ is biologically active, as shown by the ability of said isolated HIV Tat protein, ~~fragment and mutant~~ to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, and to enter and localize in the nuclei of activated endothelial cells or dendritic cells; which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, and which ability to enter and localize is determined by (a) incubating activated endothelial cells or dendritic cells with up to 1 µg/ml of said isolated HIV Tat protein which is labeled with rhodamine, and (b) detecting the presence or absence of rhodamine in the activated endothelial cells or dendritic cells by fluorescence microscopy

(iii) — ~~activate virus replication when said isolated HIV Tat protein, fragment and mutant is added to HIV-1 infected cells at a concentration of up to 1 µg/ml, which activation is determined by (a) the rescue of Tat defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein, fragment and mutant, or (b) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid.~~

147. (Currently amended) The composition of claim 146, wherein the isolated HIV Tat protein, ~~fragment and mutant~~ is a wild type HIV Tat protein.

148. (Previously presented) The composition of claim 147, wherein said wild type HIV Tat protein is purified.

149. (Currently amended) The composition of claim 147, wherein the amino acid sequence of said wild type HIV Tat protein consists of ~~SEQ ID NO: 2~~ SEQ ID NO:2.

150. (Previously presented) The composition of claim 149, wherein said wild type HIV Tat protein is purified.

151. (Previously presented) The composition of claim 146, 147, 148, or 150 which further comprises an adjuvant.

152. (Previously presented) The composition of claim 146, 147, 148, or 150, wherein the administration is intradermal.

153. (Previously presented) The composition of claim 146, 147, 148, or 150, wherein the administration is subcutaneous.

154. (Previously presented) The composition of claim 153 which further comprises Alum.

155. (Currently amended) The composition of claim 62, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is biologically active, as shown by the ability of said isolated HIV Tat protein, ~~mutant, or fragment~~ to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, and the ability of said isolated HIV Tat protein to do both of the following (i) and (ii):

- (i) ~~become internalized by~~ enter and localize in the nuclei of activated endothelial cells or dendritic cells, which ~~internalization~~ entering and localizing is determined by (a) incubating activated endothelial cells or dendritic cells with up to 1 µg/ml of said isolated HIV Tat protein, ~~fragment or mutant~~ which is labeled with rhodamine, and (b) detecting the presence or absence of rhodamine in the activated endothelial cells or dendritic cells by fluorescence microscopy; and
- (ii) activate the proliferation, migration, and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said isolated HIV Tat protein, ~~fragment or mutant~~ is present at a concentration of up to 1 µg/ml; and
- (iii) ~~activate virus replication when said isolated HIV Tat protein, fragment or mutant is added to HIV-1 infected cells at a concentration of up to 1 µg/ml, which activation is determined by (a) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein, fragment or mutant, or (b) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid.~~

156. (Currently amended) The composition of claim 155, wherein the isolated HIV Tat protein, ~~fragment or mutant~~ is a wild type HIV Tat protein.
157. (Previously presented) The composition of claim 156, wherein said wild type HIV Tat protein is purified.
158. (Currently amended) The composition of claim 156, wherein the amino acid sequence of said wild type HIV Tat protein consists of ~~SEQ ID NO: 2~~ SEQ ID NO:2.
159. (Previously presented) The composition of claim 158, wherein said wild type HIV Tat protein is purified.
160. (Previously presented) The composition of claim 155, 156, 157, or 159 which further comprises an adjuvant.
161. (Previously presented) The composition of claim 155, 156, 157, or 159, wherein the administration is intradermal.
162. (Previously presented) The composition of claim 155, 156, 157, or 159, wherein the administration is subcutaneous.
163. (Previously presented) The composition of claim 162 which further comprises Alum.
164. (Currently amended) The composition of claim 62 or 63, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ comprises the cysteine rich region of HIV Tat and is in a non-oxidated form.
165. (Previously presented) The composition of claim 92, wherein said wild type HIV Tat protein is in a non-oxidated form.
166. (Cancelled)
167. (Previously presented) The composition of any of claims 147-150, wherein said wild type HIV Tat protein is in a non-oxidated form.
168. (Previously presented) The composition of any of claims 156-159, wherein said wild type HIV Tat protein is in a non-oxidated form.

169-178. (Cancelled)

179. (Currently amended) A composition comprising: an isolated HIV Tat protein; ~~fragment or mutant~~ in combination with a pharmaceutically acceptable carrier or excipient, wherein said isolated HIV Tat protein; ~~fragment or mutant~~ is in a non-oxidated form, wherein said composition is pharmaceutically acceptable for administration to a human, ~~wherein the amino acid sequence of said mutant is SEQ ID NO:4, 6 or 8, and wherein the amino acid sequence of said fragment is SEQ ID NO:16 or 17~~ and wherein the isolated HIV Tat protein is a wild type HIV Tat protein.

180. (Cancelled)

181. (Currently amended) The composition of claim ~~180~~ 179, wherein said wild type HIV Tat protein is purified.

182. (Currently amended) The composition of claim ~~180~~ 179, wherein the amino acid sequence of said wild type HIV Tat protein consists of ~~SEQ ID NO:2~~ SEQ ID NO:2.

183. (Previously presented) The composition of claim 182, wherein said wild type HIV Tat protein is purified.

184. (Currently amended) The composition of claim 179, ~~180~~, 181, or 183 which further comprises an adjuvant.

185. (Currently amended) The composition of claim 179, ~~180~~, 181, or 183, wherein the administration is intradermal.

186. (Currently amended) The composition of claim 179, ~~180~~, 181, or 183, wherein the administration is subcutaneous.

187. (Previously presented) The composition of claim 186 which further comprises Alum.

188. (Currently amended) The composition of claim 179, wherein said isolated HIV Tat protein; ~~fragment or mutant~~ is conjugated to a T-helper peptide or T-helper universal epitope of Tetanus Toxoid.

189. (Previously presented) The composition of claim 179, which further comprises HIV rev, nef or gag, or an immunogenic fragment thereof.

190. (Previously presented) The composition of claim 179, which further comprises an immuno-modulant cytokine.

191. (Previously presented) The composition of claim 190, wherein said immuno-modulant cytokine is IL-12 or IL-15.

192. (Withdrawn – Currently amended) A composition comprising an isolated HIV Tat mutant in combination with a pharmaceutically acceptable carrier or excipient, wherein said isolated HIV Tat mutant is in a non-oxidated form, wherein the amino acid sequence of said HIV Tat mutant is ~~SEQ ID NO. 4~~ SEQ ID NO:4, and wherein said composition is pharmaceutically acceptable for administration to a human.

193. (Withdrawn – Currently amended) A method for inducing an immune response in a subject, comprising administering to said subject a composition comprising an isolated HIV Tat protein, ~~fragment or mutant~~ in combination with a pharmaceutically acceptable carrier or excipient, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is biologically active, as shown by the ability of said isolated HIV Tat protein, ~~fragment or mutant~~ to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, and the ability of said isolated Tat protein to do one or both of the following (i) and (ii):

- (i) ~~become internalized by~~ enter and localize in the nuclei of activated endothelial cells or dendritic cells, which ~~internalization~~ entering and localizing is determined by (a) incubating activated endothelial cells or dendritic cells with up to 1 µg/ml of said isolated HIV Tat protein, ~~fragment or mutant~~ which is labeled with rhodamine, and (b) detecting the presence or absence of rhodamine in the activated endothelial cells or dendritic cells by fluorescence microscopy; or

- (ii) activate the proliferation, migration, and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said isolated HIV Tat protein, ~~fragment or mutant~~ is present at a concentration of up to 1 µg/ml; ~~or~~
- (iii) ~~activate virus replication when said isolated HIV Tat protein, fragment or mutant is added to HIV-1 infected cells at a concentration of up to 1 µg/ml, which activation is determined by (a) the rescue of Tat defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein, fragment or mutant, or (b) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter reporter plasmid,~~

wherein said composition is pharmaceutically acceptable for administration to a human, ~~wherein the amino acid sequence of said mutant is SEQ ID NO:4, 6 or 8, and wherein the amino acid sequence of said fragment is SEQ ID NO:16 or 17.~~

194. (Withdrawn – Currently amended) The method of claim 193, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is purified.

195. (Withdrawn – Currently amended) The method of claim 193 or 194, wherein the isolated HIV Tat protein, ~~fragment or mutant~~ is a wild type HIV Tat protein.

196. (Withdrawn – Currently amended) A method for inducing an immune response in a subject, comprising administering to said subject a composition comprising an isolated HIV Tat protein, ~~fragment or mutant~~ in combination with a pharmaceutically acceptable carrier or excipient, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is in a non-oxidated form, wherein said composition is pharmaceutically acceptable for administration to a human, ~~wherein the amino acid sequence of said mutant is SEQ ID NO:4, 6 or 8, and wherein the amino acid sequence of said fragment is SEQ ID NO:16 or 17~~ and wherein the isolated HIV Tat protein is a wild type HIV Tat protein.

197. (Cancelled)

198. (Withdrawn – Currently amended) The method of claim 196 ~~or 197~~, wherein said isolated HIV Tat protein, ~~fragment or mutant~~ is purified.

199. (New) The composition of claim 62, wherein said isolated HIV Tat protein is biologically active, as shown by the ability of said isolated HIV Tat protein to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, and to activate the proliferation, migration, and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said isolated HIV Tat protein is present at a concentration of up to 1 µg/ml; which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml.

200. (New) The composition of claim 199, wherein the isolated HIV Tat protein is a wild type HIV Tat protein.

201. (New) The composition of claim 200, wherein said wild type HIV Tat protein is purified.

202. (New) The composition of claim 200, wherein the amino acid sequence of said wild type HIV Tat protein consists of SEQ ID NO:2.

203. (New) The composition of claim 202, wherein said wild type HIV Tat protein is purified.

204. (New) The composition of claim 199, 200, 201, or 203 which further comprises an adjuvant.

205. (New) The composition of claim 199, 200, 201, or 203, wherein the administration is intradermal.

206. (New) The composition of claim 199, 200, 201, or 203, wherein the administration is subcutaneous.

207. (New) The composition of claim 206 which further comprises Alum.